I. POLICY

Enhanced external counterpulsation is considered *investigational* for all indications, including but not limited to, treatment of chronic stable angina pectoris, heart failure, erectile dysfunction, or ischemic stroke. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

This policy only addresses the outpatient uses of EECP, i.e., for the treatment of chronic stable angina or heart failure. This policy does not address its use for unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

*Cross-reference:*
MP-1.057 Transmyocardial Revascularization

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*  BlueJourney PPO*  FEP PPO**

*Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 20.20: External Counterpulsation (ECP) for Severe Angina for coverage indications.

**Refer to FEP Medical Policy Manual MP-2.02.06 Enhanced External Counterpulsation (EECP). The FEP Medical Policy Manual can be found at: www.fepblue.org
MEDICAL POLICY

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<th>POLICY TITLE</th>
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III. DESCRIPTION/BACKGROUND

Enhanced external counterpulsation (EECP) is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. It has been studied primarily in patients with refractory angina and heart failure, as well as erectile dysfunction and ischemic stroke.

Enhanced external counterpulsation (EECP) uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. Augmenting diastolic pressure displaces a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and the resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure may enhance coronary collateral development or increase flow through existing collaterals. In addition, when the left ventricle contracts, it faces a reduced aortic pressure to work against, since the counterpulsation has somewhat emptied the aorta. EECP has been primarily investigated as a treatment for chronic stable angina.

Intra-aortic balloon counterpulsation is a more familiar, invasive form of counterpulsation that is used as a method of temporary circulatory assistance for the ischemic heart, often after an acute myocardial infarction (MI). In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the development of coronary collateral development. A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms (EKGs) to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

Regulatory Status

A variety of enhanced external counterpulsation (EECP) devices have been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. Examples of EECP devices with FDA clearance are outlined in Table 1.

Table 1: FDA-Cleared EECP Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
<th>Indications</th>
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</table>
| Renew® NCP-5 External Counterpulsation System | Renew Group (Rockville, MD) | December 2015 | • Treatment of chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization  
• In healthy patients to improve vasodilation, increase VO₂, and increase blood flow |
| ECP Health System Model       | ECP Health        | August 2005    | • Stable or unstable angina pectoris                                         |
|                               |                    |                | • Acute myocardial infarction                                                 |
|                               |                    |                | • Cardiogenic shock                                                          |
|                               |                    |                | • Congestive heart failure                                                   |
| CardiAssist™ Counter Pulsation System | Cardiomedics (Irvine, CA) | March 2005    | • Treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial |
MEDICAL POLICY

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<th>Indications</th>
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<tbody>
<tr>
<td>ACS Model NCP-2 External</td>
<td>Applied Cardiac Systems</td>
<td>August 2004</td>
<td>• Stable or unstable angina pectoris</td>
</tr>
<tr>
<td>Counterpulsation Device</td>
<td>(Laguna Hills, CA)</td>
<td></td>
<td>• Acute myocardial infarction</td>
</tr>
<tr>
<td>EECP® Therapy System</td>
<td>Vasomedical (Westbury, NY)</td>
<td>March 2004</td>
<td>• Cardiogenic shock</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Congestive heart failure</td>
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<td></td>
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<td>• Congestive heart failure</td>
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</tbody>
</table>

EECP: enhanced external counterpulsation; FDA: Food and Drug Administration; VO_2: oxygen consumption.

FDA product code: DRN.

IV. RATIONALE

Randomized controlled trials (RCTs) that report on relevant clinical outcomes are required to determine whether enhanced external counterpulsation (EECP) is efficacious and whether it is at least as good as alternative treatments. Observational data are of limited utility given the variable natural history of disorders (e.g., angina, heart failure), the presence of many potential confounders of cardiac outcomes, and the potential for a placebo effect.

The literature base consists of a small number of RCTs, some of which have reported relevant clinical outcomes and others that have reported intermediate, or physiologic, outcome measures. In addition, there are a large number of observational studies, including publications from EECP registries and case series that have generally reported pre- and posttreatment measures of EECP effectiveness.

Chronic Stable Angina

TEC Assessments
The original literature review for this review was based on a 1999 TEC Assessment on EECP for chronic stable angina, which was updated in 2002 and 2005. These assessments concluded that the evidence was insufficient to determine whether EECP improved the net health outcome or was as beneficial as any established alternatives in patients with chronic stable angina.

Specifically, the 2005 TEC Assessment offered the following observations and conclusions regarding EECP for chronic stable angina:\(^1,2\):

- There was insufficient evidence to draw conclusions about the benefits of EECP.
- The results of the single RCT, the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP), must be interpreted with caution, in view of the high subject dropout rate and uncertainty regarding the clinical significance of the reported improvement in physiologic measures, especially when intention-to-treat (ITT) analysis is applied.\(^3,4\)
Comparative studies of EECP did not address the hard outcomes of cardiac death or recurrent cardiac events such as myocardial infarction and revascularization procedures.\(^5,6\)

Several case series and registry-based studies have reported the outcomes of large numbers of patients treated in a number of different institutions. There were several problems with this kind of evidence. These studies, while contributing to the body of knowledge of EECP, did little to address the efficacy or durability of EECP treatment. The lack of comparison groups made it impossible to rule out either placebo effect or spontaneous recovery among patients with milder disease.

**Randomized Controlled Trials**

In 1999, Arora et al presented results of the MUST-EECP trial.\(^3\) MUST-EECP applied a randomized controlled, double-blinded protocol that compared active treatment to placebo (inactive counterpulsation [CP] sham treatment) among 139 patients with Canadian Cardiovascular Society (CCS) Classification Scales (a functional assessment tool based on the level of exertion that elicits symptoms) class I, II, or III chronic, stable angina. Four outcomes were examined: (1) self-reported frequency of angina, analyzed 2 ways; (2) self-reported use of on-demand nitroglycerin; (3) exercise duration tolerance testing; and (4) time to exercise-induced ischemia (defined as time to depression of ≥1mm in the ST segment on electrocardiogram).

All patients underwent the same 35-hour protocol, followed by an exercise tolerance test within 1 week of completing therapy. Follow-up beyond the treatment period was not conducted. ITT analyses were reported for the angina count and nitroglycerin usage outcomes only. There was a statistically significant difference (p=0.01) between groups in the change in time to 1 mm or greater ST segment depression. Patients in the EECP group had an average difference of 37 seconds longer time to ST segment depression compared with the sham-treated group. There was no significant difference between treatment groups in the change in exercise duration from baseline to the posttreatment period (p<0.31). In addition, there were no statistically significant differences between groups with respect to angina counts (p<0.09) or nitroglycerin use (p>0.1).

In addition to methodologic limitations found in the design, execution, and reporting of this study, the magnitude of the benefit reported is not large. Of the 4 end points of interest, only time to ST segment depression differed statistically in the EECP group compared with the sham group. The clinical significance of a 37-second improvement in time to ST segment depression is unknown, but given that it occurred while the other 3 end points were statistically unchanged with therapy, does not suggest a marked improvement. That both groups showed increased exercise duration suggests a degree of placebo effect; exercise duration possesses a motivational component that time to ST segment depression does not.

In 2002, Arora et al published a 12-month follow-up study to the MUST-EECP trial.\(^4\) Only 71 (54%) of the original 139 subjects were included in the study. Subjects treated with EECP reported greater improvement in several quality-of-life (QOL) scales. However, such findings could not be correlated with treatment response reported in the first study (because of data...
limitations). The findings were further limited by the small sample size and potentially biased sample of the original subject pool.

A small unblinded RCT published in 2011 addressed 1 health outcome (change after 7 weeks in CCS angina class), along with multiple intermediate outcomes. Twenty patients with refractory angina (CCS class III) were randomized to EECP or no EECP. Mean CCS class was significantly improved in the EECP group but not in the no-EECP group. At 7-week follow-up, soluble interleukin-2 receptor measurements significantly increased in the EECP group and significantly decreased in the no-EECP group. There were no differences between groups at 7 weeks in resting cutaneous microvascular blood flow or response to acetylcholine, sodium nitroprusside, or local heating.

Additional RCTs have reported on intermediate, or physiologic, outcomes. One such RCT (N=20), published in 2010, compared intracoronary blood flows in patients treated with EECP to those treated with a sham procedure. This trial was designed to detect statistically significant differences in collateral flow rates by angiography, not anginal symptoms. After 7 weeks of treatment, collateral flow index increased significantly in the EECP group compared with sham treatment. Similar findings were noted in a 2009 comparative study by Buschmann et al of 23 patients.

Two publications from a single trial reported on blood flow and other measures of arterial function. This study randomized 42 patients with coronary artery disease (CAD) and chronic angina to EECP or sham EECP. EECP improved flow-mediated dilation in the brachial and femoral arteries and improved numerous serum markers of blood flow and inflammation. The same study also reported that measures of arterial stiffness were improved in the EECP group.

In a 2015 randomized pilot study, Shakouri et al reported on intermediate outcome measures, including plasma nitric oxide, endothelin 1, high-sensitivity C-reactive protein, and QOL, in patients with CAD allocated to 20 sessions of EECP (n=21) or cardiac rehabilitation (n=21). There were no statistically significant improvements in physiologic markers and QOL over time in either group and no statistically significant between-group differences in change in any of the parameters evaluation.

**Systematic Reviews**

Systematic reviews of the literature have evaluated EECP for chronic stable angina. In 2010, Amin et al published a Cochrane review of major databases through 2008 on evidence of the effectiveness of EECP for chronic angina pectoris. The solitary RCT identified was the MUST-EECP trial. The reviewers highlighted patient selection for this study. They noted that limiting the study population to patients with CCS class below IV diminished the trial’s generalizability to patients of interest, i.e., patients with the most severe symptoms of chronic angina pectoris.

Also in 2010, Shah et al published a meta-analysis of prospective studies, not limited to RCTs, of EECP in stable angina in which CCS class was adequately reported before and after treatment. The MUST-EECP RCT was not included, because change in CCS class was not a reported outcome. A total of 13 studies met these inclusion criteria (total N=949 patients). Overall, improvement of at least 1 level of angina class occurred in 86% of patients (95% confidence
interval [CI], 82% to 90%; p=0.008). No conclusions can be drawn from this analysis given the lack of randomization (comparison group) for most studies analyzed.

In 2009, McKenna et al report on a systematic review and economic analysis of EECP for the treatment of stable angina and heart failure. Four studies (1 RCT, 3 nonrandomized comparative studies) comparing EECP treatment with no treatment in adults with chronic stable angina were selected. The systematic review included a study by Barsheshet et al in which 25 patients (15 EECP, 10 controls) were evaluated at the end of treatment. Similar to the Schechter et al study, "CCS classification improved with EECP but not with usual care, however statistical analysis of between group differences was not reported and, for CCS classification, the data were treated as continuous data which is inappropriate for this four-category classification."

A 2016 systematic review and meta-analysis focused on the effect of EECP on the intermediate measure of myocardial perfusion in patients with CAD. The review included 6 studies reporting on myocardial perfusion or coronary flow outcomes published from 1992 to 2007, including 5 RCTs and 1 prospective, observational, blinded study. In pooled analysis, EECP was associated with increased myocardial perfusion in CAD patients (pooled weighted mean difference, -0.19; 95% CI, -0.38 to 0.00; p=0.049).

**Registry Studies**

Registry-based studies have reported on relatively large numbers of patients. In 1 registry-based study, 450 patients with left ventricular dysfunction (ejection fraction, ≤40%) and refractory angina had 0.7 fewer emergency department visits and 0.8 fewer hospitalizations 6 months after treatment with EECP compared with the 6 months before EECP; 6-month data were available on only 81 patients. Drawing conclusions from this study is not possible due to lack of a comparison group.

Another registry-based study (the International Enhanced External Counterpulsation Patient [IECP] Registry) reported 3-year results for patients with chronic refractory angina. The registry enrolled 5000 patients from 99 U.S. and 9 international centers between 1999 and 2001. However, analysis was completed only for those centers that had at least 80% compliance with follow-up data submission; the study reported results on 1427 patients. In this select group, 220 (15.4%) patients died, while 1061 (74.4%) patients completed their follow-up. Immediately post-EECP, the proportion of patients with severe angina (CCS class III/IV) were reduced from 89% to 25% (p<0.001). This improvement was sustained in 74% of the patients during follow-up. More severe baseline angina and a history of heart failure or diabetes were independent predictors of unfavorable outcome. Again, the lack of a control group in this study precludes drawing conclusions about this technology.

IECP data have also been examined to determine the safety and efficacy of this device in patients with peripheral arterial disease (PAD). PAD, while a common comorbidity of CAD, has been regarded as a contraindication to EECP due to concerns about compression on peripheral blood flow and a potentially greater risk of aortic rupture. Thakkar et al compared registry data in patients with PAD to those without. Based on a reduction of 1 or more CCS angina classes, patients with PAD had a similar rate of improvement as did the group without PAD (76.6% vs
79.0%, respectively; p=0.27). Rates of hospitalization for all cardiac causes (6.1% vs 4.4%, respectively; p=0.17) and for unstable angina (5.4% vs 3.5%, respectively; p=0.25) were also similar between groups.

**Other Observational Studies**
Numerous individual observational studies have been detailed in previous reviews and are included in systematic reviews previously described.4-6,9,16,21 For example, 2 prospective cohort studies (N=55 and N=61) with 1-year outcomes have been reported.22,23 Improved CCS classification was the main reported outcome, which was maintained for 1 year in 79% and 78% of patients in the respective studies. Both studies had higher rates of treatment completion and follow-up than the previously reported (registry) studies of long-term outcomes. These studies address the need for data on treatment durability.

**Section Summary: Chronic Stable Angina**
Data on use of EECP in chronic stable angina are insufficient to form conclusions about the efficacy of this treatment. The single randomized trial (MUST-EECP) that included relevant clinical outcomes reported a benefit on 1 of 4 main angina-related outcomes, and the magnitude of this benefit was of uncertain clinical significance. RCTs have reported on intermediate outcomes offer evidence on possible physiologic mechanisms underlying EECP treatment but do not themselves provide evidence of health outcome benefits. Observational studies (e.g., registry data, case series) offer little evidence on the efficacy of this procedure due to the variable natural history of angina, the multiple confounders of cardiac outcomes, and the potential for a placebo effect.

**Heart Failure**
The 510(k) approval of the Vasomedical devices stated that objective measures, such as peak oxygen consumption (\(V_{O_2}\)peak), exercise duration, and preload-adjusted maximal left ventricular power, are improved following EECP therapy, as are subjective measures of patient response to therapy, such as QOL and functional ability.24 However, no clinical details of these studies were provided in the Food and Drug Administration summary, and these data were not from controlled trials.

The 2005 TEC Assessment included heart failure in its analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure was lacking in both quantity and quality.11 A single randomized, multicenter study compared EECP to usual care in 187 optimally medically managed patients with New York Heart Association (NYHA) functional class II or III heart failure with an ejection fraction of 35% or less of ischemic or idiopathic etiology. This study, the Prospective Evaluation of EECP in Congestive Heart Failure (PEECH trial), was mostly inconclusive.25 The design and methods of the PEECH trial were published by Feldman et al.24 PEECH trial results found statistically improved, but modest, changes in exercise duration and improved functional class but not in QOL or \(V_{O_2}\)peak.25 A subgroup analysis of the PEECH trial showed that subjects ages 65 years and older treated with EECP (n=41) were more likely to meet the exercise duration (35% vs 25% increased by ≥60 seconds) and \(V_{O_2}\)peak (30% vs 11% increased by ≥1.25 mL/kg/min) improvement thresholds.
compared with those undergoing sham treatment (n=45); there was no difference at 6 months in NYHA class.²

In 2015, Rampengan et al reported on a double-blinded RCT evaluating EECP in patients with CHF treated in Indonesia.²⁶ Patients with NYHA functional class I or II symptomatic heart failure from various causes were included. Patients were randomized to active EECP (n=56) or sham EECP (n=56), which involved the use of the EECP device at only 77 mm Hg of pressure versus the standard 300 mm Hg. Analysis was per protocol, excluding 6 and 7 patients who dropped out of the active and sham groups, respectively. Postintervention, active EECP group patients were more likely to have a 6-minute walk test (6MWT) distance of 300 meters or greater (98.0% vs 32.7%, p<0.01). The change in 6MWT distance was greater (improved) for the active EECP patients (192.6 meters) than for the sham control patients (-9 meters; p<0.05).

Similar to the registry evidence for EECP for angina, registry studies for heart failure have provided relatively little insight into the comparative efficacy of EECP.²⁷-³⁰ The single-arm study by Soran et al indicated that patients showed some improvements, but the lack of a comparison arm precludes inferences about the true effects of therapy.³¹

The previously described 2009 review by McKenna et al¹⁵ included the single trial of EECP for heart failure available at that time, the PEECH study.²⁵ The authors concluded that the studies did not provide firm evidence of the clinical effectiveness of EECP in refractory stable angina or in heart failure and that high-quality studies are required to investigate the benefits of EECP and whether they outweigh the common adverse effects.

**Section Summary: Heart Failure**
The evidence for the use of EECP in heart failure includes 2 RCTs that was reported on clinical outcomes. One study reported modest improvements for some outcomes and no improvement on others. A second study reported improvements in the 6MWT, but has methodologic limitations that limit conclusions that can be drawn. The observational studies added little to the evaluation of efficacy due to the variable natural history of heart failure, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect. Further high-quality RCTs are needed to determine whether EECP is a useful treatment for heart failure.

**Other Indications**
The use of EECP for other conditions associated with ischemia or vascular dysfunction has been investigated. In 2009, Fraser and Adams produced a Cochrane review on interventions for central retinal artery occlusion (CRAO).³² One of the 2 RCTs identified compared hemodilution with EECP against hemodilution without further intervention. In this case, the EECP intervention was a single, 2-hour treatment. According to the reviewers, in this study, 20 patients were randomized but not blinded; no sham treatment was given. Primary outcomes were Doppler flowmetry of retinal perfusion and visual acuity.³³

Published registry studies have also demonstrated improvements in erectile function.³⁴ Erectile function was improved in a study of 120 men prospectively enrolled from 16 centers. Three of 5 domains of the International Index of Erectile Function were statistically improved with EECP treatment (erectile function, intercourse satisfaction, overall satisfaction), and the total score
improved from 28 to 32, a statistically significant improvement. The noncomparative design of this study makes it difficult to draw conclusions on treatment efficacy. Preliminary studies from Asia are also reporting early results on use of EECP to the lower extremities in the treatment of acute ischemic stroke. A 2012 Cochrane review of 2 RCTs of EECP in acute ischemic stroke concluded that the methodologic quality of the studies was poor and reliable conclusions could not be reached from this evidence.

In 2016, Sardina et al reported on an RCT that randomized 30 patients with type 2 diabetes in a 2:1 ratio to EECP (n=20) or standard care for diabetes (n=10), and reported results out to 3 and 6 months. At 6-month follow-up, patients in the EECP group had significant decreases over time in variety of biomarkers of advanced glycation end products, inflammation, and oxidative stress. At 6-month follow-up, the percent change in advanced glycation end products and receptor of advanced glycation end products differed significantly between groups (p<0.05).

### Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

### Summary of Evidence
For individuals who have chronic stable angina who receive enhanced external counterpulsation (EECP), the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. There is only 1 blinded RCT that includes clinical outcomes, and it reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs have reported changes in physiologic measures associated with EECP but did not provide relevant evidence on clinical efficacy. Because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect, RCT evidence is needed. Therefore, observational studies, including registry studies with large numbers of patients, add little to determinations of efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure who receive EECP, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. One RCT that reported on clinical outcomes found a modest benefit with EECP on some outcomes and no benefit on others. A second RCT reported improvements on the 6-minute walk test with EECP, but had methodologic limitations that limit conclusions that can be drawn. The observational studies on EECP in heart failure have limited ability to inform the evidence on EECP due to the multiple confounding variables for cardiac outcomes and the potential for a placebo effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate
In response to requests, input was received from 3 academic medical centers while this policy was under review, one during review in April 2008, one during review in October 2008, and one during review in 2009. Reviewers agreed with the conclusion that EECP was investigational. Some reviewers commented about potential use of EECP in those with angina not amenable to surgical interventions.

**Practice Guidelines and Position Statements**

Guidelines from the American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and 5 other medical societies in 2012 guidelines on the management of patients with stable ischemic heart disease indicated EECP “may be considered for relief of refractory angina.” This recommendation was based on class IIb, level of evidence: B, which indicates the efficacy of the intervention is not well established and further studies would be helpful. 39

The 2013 ACCF and AHA guidelines on the management of heart failure do not address EECP. 40

In 2014, ACC and AHA issued a Focused Update on the 2012 guideline on the diagnosis and management of patients with stable ischemic heart disease in which the associations specifically reviewed their recommendation on EECP. Based on this review, the recommendation on EECP remained unchanged from the 2012 guideline. 41

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

Medicare has published a national coverage decision (NCD) on EECP that mandates coverage for the following indications42:

“Coverage is provided for the use of EECP for patients who have been diagnosed with disabling angina who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty or cardiac bypass because: 1) Their condition is inoperable, or at high risk of operative complications or post-operative failure; 2) Their coronary anatomy is not readily amendable to such procedures; or 3) They have co-morbid states which create excessive risk.”

Medicare’s coverage policy also notes that while the U.S. Food and Drug Administration has cleared EECP “for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered….”

This Medicare NCD differs from the BCBSA determination of medical necessity. The discrepancy primarily arises from different interpretations of the MUST-EECP trial.
original Centers for Medicare and Medicaid Services NCD issued in November 1999,\(^4\) the conclusion was that, based on the results of MUST-EECP, EECP was reasonable and necessary for patients with severe angina refractory to medical and/or surgical intervention. Subsequent reanalyses of this decision in 2001 and 2006\(^2\) did not result in any changes to the coverage position. In contrast, a TEC Assessment performed in 1999 concluded that evidence from the MUST-EECP trial was not sufficient to permit conclusions on the impact of the technology (see the Rationale section for TEC conclusions on the MUST-EECP trial). Subsequent TEC Assessments in 2002 and 2005,\(^1\) which considered the MUST-EECP trial plus other evidence, also concluded that the evidence was not sufficient to permit conclusions

### V. Definitions

**AFTERLOAD** is the load or resistance, against which the left ventricle must eject its volume of blood during contraction. The resistance is produced by the volume of blood already in the vascular system and the vessel walls.

**DIASTOLE** is the normal period in the heart cycle during which the muscle fibers lengthen, the heart dilates, and the cavities fill with blood.

### VI. Benefit Variations

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

### VII. Disclaimer

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

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<tr>
<th>HCPCS Code</th>
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<tbody>
<tr>
<td>G0166</td>
<td>External Counterpulsation, Per Treatment Session</td>
</tr>
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</table>

IX. REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). External Counterpulsation for Treatment of Chronic Stable Angina Pectoris and Chronic Heart Failure. TEC Assessments. 2005;20;Tab 12.


Other Sources:

Taber’s Cyclopedic Medical Dictionary, 19th edition.

X. POLICY HISTORY

| MP 2.014 | CAC 1/28/03 CAC 10/28/03 CAC 8/31/04 CAC 8/30/05 CAC 4/25/06 CAC 3/27/07 CAC 5/27/08 CAC 5/26/09 CAC 5/25/10 Consensus CAC 4/26/11 Consensus CAC 2/28/12 Adopt BCBSA. Procedure now considered investigational; previously considered medically necessary, Policy title revised from Enhanced External Counterpulsation (EECP) to Enhanced External Counterpulsation (EECP) for Chronic Angina or Heart Failure. FEP variation revised. CAC 3/26/13 Consensus review. References updated but no changes to the policy statement. Codes reviewed. CAC 1/28/14 Consensus. No change to policy statements. References updated. Rationale section and Policy guidelines added. Changed title - was Enhanced External Counterpulsation (EECP) for Chronic Stable Angina or Heart Failure. CAC 1/27/15 Consensus. No change to policy statements. References and rationale updated. CAC 1/26/16 Consensus. No change to policy statements. References and rationale updated. Coding updated. Admin update 1/1/17: Product variation section reformatted. CAC 3/28/17 Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed. |